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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/035,397	10/25/2001	Bret A. Shirley	PP17201.003 (35784/240412)	3374
7590	03/23/2004		EXAMINER	
Chiron Corporation Intellectual Property Department P.O. Box 8097 Emeryville, CA 94662-8097			ANDRES, JANET L	
			ART UNIT	PAPER NUMBER
			1646	

DATE MAILED: 03/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/035,397

Applicant(s)

SHIRLEY ET AL.

Examiner

Janet L. Andres

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-108 is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) See Continuation Sheet is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>26 January 2004</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims withdrawn from consideration are 7-10,12,19-22,27-30,41,42,45,46,49,50,53-56,59-67,75-81,85,87,95 and 97.

Continuation of Disposition of Claims: Claims rejected are 1-6,8,11,13-18,23-26,31-40,43,44,47,48,51,52,57,68-74,82-84,86,88-94,96 and 98-108.

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RESPONSE TO AMENDMENT

1. Applicant's amendment filed 30 December 2003 is acknowledged. Claims 1-108 are pending in this application. Claims 7-10, 12, 19-22, 27-30, 41, 42, 45, 46, 49, 50, 53-56, 59-67, 75-81, 85, 87, 95, and 97 are withdrawn from consideration as being drawn to non-elected species. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

Claim Rejections/Objections Withdrawn

2. The objection to the specification is withdrawn in response to Applicant's amendment adding the serial number of the priority application.

3. The rejection of claims 1-6, 8, 11, 13-18, 23-26, 31-40, 43, 44, 47, 48, 51, 52, 57, 58, 68-74, 82-84, 86, 88-94, 96, and 98-102 under 35 U.S.C. 103(a) as being unpatentable over Hershenson et al. in view of U.S. patent 6,525,102 is withdrawn in response the statement by Applicant's representative that the application and reference were owned by or assigned to the same person.

Claim Rejections Maintained/New Grounds of Objection

4. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code on p. 18, line 1. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

5. The rejection of claims 1-6, 8, 11, 13-18, 23-26, 31-40, 43, 44, 47, 48, 51, 52, 57, 68-74, 82-84, 86, 88-94, 96, and 98-102 is maintained for reasons of record in the office action of 4 September 2003 and applied to new claims 103-108.

Applicant argues that Hershenson teaches that their formulation contains soluble IFN- β but does not disclose that a portion is monomeric and a portion is present as an aggregate. Applicant further argues that Hershenson requires the use of stabilizers. Applicant argues that the Merck index does not suggest the use of aspartic acid with IFN- β and particularly does not teach its use to maintain IFN- β in substantially monomeric form. Applicant additionally states that only one page of the Merck Index has been provided. With respect to the new claims, Applicant argues that Hershenson does not teach stabilization.

Applicant's arguments have been fully considered but have not been found to be persuasive. It is not necessary that Hershenson teach an inherent property of Hershenson's formulation. Since the teachings of Hershenson anticipate all of Applicant's conditions except the particular buffer used, unless that buffer is crucial to the prevalence of monomers, Hershenson teaches a formulation that has the characteristics claimed by Applicant. It is not necessary that those characteristics be recognized for them to exist. The buffer claimed by Applicant, aspartic acid, is, by Applicant's own teachings, not crucial. On p. 6, lines 11-15, Applicant lists many buffers, including phosphate (line 14), which is the preferred buffer of Hershenson. Thus the aspartic acid is not responsible for the monomeric condition of the IFN- β and it is an inherent property of the formulations of Hershenson. With respect to Applicant's arguments that the formulations of Hershenson require stabilizers, Applicant's claims do not exclude them and claims 15-18, 23-30, 88, 98 require the presence of trehalose, which is taught by Hershenson in column 9, lines 21-31 to be a stabilizing agent. With respect to Applicant's argument that the Merck Index does not teach the combination of aspartic acid with IFN- β , one cannot show nonobviousness by attacking references individually where the rejections are based

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on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Hershenson teaches a formulation for IFN- β and the Merck Index teaches a compound that one of ordinary skill would readily recognize as useful in such a formulation, since it is a weak acid with an appropriate pKa. Only the relevant page of the Merck Index was provided because it exceeds 1600 pages in length. It should, however, have been noted by the Examiner that only one page would be provided and the omission is regretted.

That Hershenson does not teach that the formulations are stable, as Applicant argues with respect to the new claims, does not serve to distinguish Applicant's invention. As stated above, the increased stability is an inherent property of the formulation and need not have been recognized. It is noted that new claims 103 and 104 specify a buffer concentration within the range taught by Hershenson. MPEP §2144.05 states:

Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

In the instant claims, a concentration within the range taught by Hershenson is specified and the specification does not teach that this concentration is critical; it is not even exemplified. Thus specifying this particular concentration does not support the patentability of the invention.

6. Claims 1-6, 8, 11, 13-18, 23-26, 31-40, 43, 44, 47, 48, 51, 52, 57, 68-74, 82-84, 86, 88-94, 96, and 98-108 are newly rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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These claims encompass “biologically active” variants. The specification states on p. 18, lines 23-24, that

Biologically active variants of IFN-beta encompassed by the invention should retain IFN-beta activities, particularly the ability to bind to IFN-beta receptors.

This statement does not serve to define such variants because it only lists preferred, not required properties. Thus the artisan would be unable to determine what properties, and thus what molecules, Applicant intended the claims to encompass.

NO CLAIM IS ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Andres whose telephone number is 571-272-0867. The examiner can normally be reached on Monday-Thursday and every other Friday, 8:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Janet L. Andres, Ph.D
19 March 2004


JANET ANDRES
PATENT EXAMINER